



Highlights of FDA Activities – 2/1/2020 – 2/29/2020

FDA Drug Safety Communications & Drug Information Updates:

FDA Laboratory Testing Results for NDMA Levels in Metformin – No Recalls Recommended 2/3/20

The United States Food and Drug Administration released laboratory results showing N-Nitrodimethylamine (NDMA) levels in some metformin products. The results show that the levels of NDMA range from not detectable to low levels. No sample of metformin tested by the FDA exceeded the acceptable daily intake for NDMA, the FDA has not recommended recalls of metformin. Monitoring of NDMA levels in metformin and other products will continue.

FDA Requests Withdrawal of Weight loss drug Belviq, Belviq XR (Lorcaserin) 2/13/20

Following review of clinical data about a possible risk of cancer associated with lorcaserin, the FDA requested the manufacturer voluntarily withdraw the drug from the market.

Rx-to-OTC Switch Approved – Drug Information Update 2/14/20

The FDA approved the prescription to over-the-counter switch for Voltaren Arthritis Pain (diclofenac sodium topical gel, 1%) for the temporary relief of arthritis pain; Pataday Twice Daily Relief (olopatadine HCl ophthalmic solution 0.1%) for the temporary relief of itchy and red eyes due to pollen, ragweed, grass, animal hair or dander; and Pataday Once Daily Relief (olopatadine HCl ophthalmic solution 0.2%) for the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair or dander.

FDA Launches New Purple Book Searchable Database of Biosimilars 2/24/20

The FDA released a searchable online database of FDA-approved biologic and biosimilar treatments: “Purple Book: Database of FDA-Licensed Biological Products” at <https://purplebooksearch.fda.gov>. The static pdf list will remain available until the FDA has completed transition of information for all FDA-licensed biological products.

FDA Launches Pharmacogenetic Table 2/25/20

The FDA launched a table documenting pharmacogenetic associations for which data is available to support therapeutic management recommendations (<https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations>). The table will be updated periodically with associations supported by sufficient scientific evidence.

Coronavirus (COVID-19) Supply Chain Update 2/27/20

The FDA announced the first drug shortage related to a site affected by coronavirus, due to an issue with manufacturing of an active pharmaceutical ingredient used in the drug. Although the specific product was not mentioned, further shortages are possible and the FDA has identified four strategies that may be used to prevent or mitigate medical product shortages: lengthening of expiration dates, requiring risk management plans from application holders of certain drugs, improving data sharing and requiring more accurate supply chain information, and establishing reporting requirements for device manufacturers.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

MiniMed 600 Series Insulin Pumps, Medtronic: Recall – Incorrect Insulin Dosing 2/12/20

Medtronic recalled the 600 Series MiniMed insulin pumps due to a missing or broken retainer ring that locks the insulin cartridge into the pump’s reservoir compartment. When the cartridge is not properly locked into place, over or under dosing of insulin may occur. Medtronic has received 26, 421 complaints in which the pump malfunctioned in this manner, resulting in 2,175 injuries and 1 death.

Phenytoin Oral Suspension, USP, Taro Pharmaceuticals USA, Inc.: Recall – May not Re-Suspend 2/21/20
Taro Pharmaceuticals USA, Inc. recalled two lots of phenytoin oral suspension USP, 125 mg/5 mL in 237 mL bottles (Lot #s 327874 and 327876) to the consumer level as the suspension may not re-suspend when shaken.

Ranitidine Tablets 150 mg, American Health Packaging: Recall – NDMA Impurity 2/27/20
American Health Packaging recalled eleven lots of ranitidine tablets, USP 150 mg in 100 count unit dose blisters due to potential N-nitrosodimethylamine (NDMA) amounts exceeding FDA allowed. The full list of recalled lots can be found on the FDA [site](#).

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

<u>Product</u>	<u>Promoted Use</u>	<u>Undeclared Ingredient(s) or Contaminants</u>
Alpha-Male	Sexual enhancement	Sildenafil and tadalafil ¹
Bow and Arrow*	Sexual enhancement	Sildenafil ¹
OrgaZEN Gold 5800	Sexual enhancement	Sildenafil ¹
RMFLEX	Joint pain and arthritis	Diclofenac ²
Up2*	Sexual enhancement	Sildenafil ¹
XXX Platinum WOODIE	Sexual enhancement	Sildenafil and tadalafil ¹

*recalled

¹Sildenafil and tadalafil may interact with nitrates to lower blood pressure to dangerous levels and interact with other medications such as nitrates.

²Diclofenac is a non-steroidal anti-inflammatory drug (NSAID). NSAIDs may cause increased risk of cardiovascular events as well as gastrointestinal damage. This hidden ingredient may also interact with other medications and increase the risk of adverse events.

New Product Shortages

Date Initially Posted

Pindolol tablets 2/21/20
Ceftazidime and avibactam for injection (Avycaz, Allergan) 2/26/20

Product Discontinuations/Withdrawals

Date Posted

Diclofenac Sodium 1% Topical Gel (Endo); remains available from other manufacturers 2/13/20
Didanosine delayed-release capsules USP (Videx EC, Bristol Myers Squibb); remains available from other manufacturers 2/24/20
Donepezil Hydrochloride 23 mg Tablets (Teva); remains available from other manufacturers 2/13/20
Entecavir Tablets (Teva); remains available from other manufacturers 2/14/20
Fludarabine Phosphate for Injection (Hospira, Inc.); remains available from other manufacturers 2/10/20
Fluorouracil Injection (Teva); remains available from other manufacturers 2/10/20
Levofloxacin tablets (Sandoz); remains available from other manufacturers 2/26/20
Lisinopril 10 mg and 20 mg (Prinivil, Merck Sharp & Dohme Corp); remains available in other strengths, and from other manufacturers 2/20/20
Olopatadine HCl ophthalmic solution (Pataday, Novartis); product will now be available OTC 2/26/20
Sumatriptan Succinate Injection 6 mg/0.5 mL single-dose vials (Mylan Institutional); remains available from other manufacturers 2/21/20

<u>New Drug Approvals:</u>	<u>Description (See Attached Drug Summaries)</u>	<u>Date Approved</u>
Lactitol Monohydrate Oral Solution / Pizensy / Braintree Labs	Osmotic laxative for treatment of chronic idiopathic constipation in adults	2/12/20
Bempedoic acid / Nexletol / Esperion Therapeutics Inc.	Adenosine triphosphate-citrate lyase inhibitor for use as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who required additional LDL-C lowering	2/21/20
Eptinezumab-jjmr / Vyepti / Lundbeck Seattle BioPharmaceuticals, Inc.	Calcitonin gene-related peptide antagonist for prevention of migraine in adults	2/21/20
Amisulpride / Barhemsys / Acacia Pharmaceuticals Ltd	Dopamine-2 antagonist for prevention and treatment of postoperative nausea and vomiting	2/26/20
Rimegepant / Nurtec ODT / Biohaven Pharmaceuticals	Calcitonin gene-related peptide receptor antagonist for acute treatment of migraine	2/27/20

<u>New Indications:</u>	<u>Description</u>	<u>Date Approved</u>
Dulaglutide / Trulicity / Eli Lilly & Co	To reduce risk of major adverse cardiovascular events in adults with type 2 diabetes who have established cardiovascular disease or multiple cardiovascular risk factors	2/21/20
Neratinib / Nerlynx / Puma Biotechnology Inc	For use in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting	2/25/20

<u>New Dosage Forms or Formulation:</u>	<u>Description</u>	<u>Date Approved</u>
Pemetrexed injection / Pemfexy / Eagle Pharmaceuticals, Inc.	Injection solution: 500 mg/20 mL (25 mg/mL) ready to dilute pemetrexed formulation	2/8/20
Cysteamine bitartrate delayed-release oral granule packets / Procysbi / Horizon Therapeutics USA, Inc.	Delayed-release oral granules: 75 mg and 300 mg in single-use packets; for use in nephropathic cystinosis	2/14/20
Levonorgestrel and ethinyl estradiol / Twirla / Agile Therapeutics Inc.	Transdermal system: 120 mcg/day levonorgestrel and 30 mcg/day ethinyl estradiol; contraceptive for use in women of reproductive potential with a BMI less than 30 kg/m ² (limitation of use: consider the reduced effectiveness in women with BMI of 25 or greater before prescribing)	2/14/20
Meloxicam injection / Anjeso / Baudax Bio Inc.	Injection: 30 mg/mL (30 mg) single-dose vial; IV bolus administration for management of moderate-to-severe pain, alone or in combination with a non-NSAID analgesic (see attached drug summary)	2/20/20
Adjuvanted quadrivalent influenza vaccine / Fluad Quadrivalent / Seqirus	Quadrivalent adjuvanted influenza vaccine for use in adults age 65 and older	2/24/20
Bempedoic acid, ezetimibe / Nexlizet / Esperion Therapeutics Inc.	Tablet: 180 mg bempedoic acid/10 mg ezetimibe; an adjunct to diet and maximally tolerated statin therapy for adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional LDL-C lowering	2/26/20
Ibuprofen, acetaminophen / Advil Dual Action / Pfizer	OTC Tablet: 125 mg ibuprofen/250 mg acetaminophen; for temporary relief of minor aches and pains in patients 12 years and older dosed as 2 caplets every 8 hours	2/28/20

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Lactitol Monohydrate / Pizensy / Braintree Labs	
Generic Name / Brand Name / Company	Lactitol Monohydrate / Pizensy / Braintree Labs
Date of approval	2/12/20
Drug Class (Mechanism of Action if novel agent)	Osmotic laxative
Indication	Chronic Idiopathic constipation in adults
Comparative agent – Therapeutic interchange?	Lactulose
Dosage forms/strengths	Powder for oral solution in 280 g and 560 g multidose bottles and 10 g unit dose packets
Common Dose/sig	20 grams orally once daily, preferably with meals; reduce dose to 10 mg for persistent loose stools
DEA Schedule	None
Date of market availability	Not announced
Similar Medication Names	Lactinex, Lactulose,
Clinical Use Evaluation	
Common Adverse Effects	≥3%: upper Respiratory tract infection, flatulence, diarrhea, increased blood creatinine phosphokinase, abdominal distension, and increased blood pressure.
Severe Adverse Effects	Severe diarrhea
Severe Drug-Drug Interactions	May reduce absorption of concomitant oral medications; administer oral medications at least 2 hours before or 2 hours after lactitol
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Lactitol is minimally absorbed; no dosage adjustments are recommended.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated 1) known or suspected mechanical gastrointestinal obstruction. 2) galactosemia
Special administration technique or considerations	Fill measuring cap twice to top the top of the white section in cap marked by the arrow for 20 g dose. Pour into empty glass. Add 4 to 8 ounces of water, juice, or other common beverage (coffee, tea, soda) and stir to dissolve. Drink entire contents of glass.
Prepared by	Jesse Tegtmeyer
Source	Pizensy (lactitol) [prescribing information]. Braintree, MA: Braintree Laboratories, Inc.; February 2020.

Meloxicam injection / Anjeso / Baudax Bio Inc.	
Generic Name / Brand Name / Company	Meloxicam injection / Anjeso / Baudax Bio Inc.
Date of approval	2/20/20
Drug Class (Mechanism of Action if novel agent)	NSAID; inhibition of cyclooxygenase (COX-1 and COX-2)
Indication	Treatment of moderate-to-severe pain in adult patients, alone or in combination with non-NSAID analgesics
Comparative agent – Therapeutic interchange?	Injectable NSAIDs – ketorolac, diclofenac
Dosage forms/strengths	Injection: 30 mg/mL single-dose vial
Common Dose/sig	30 mg once daily by intravenous bolus over 15 seconds
DEA Schedule	None
Date of market availability	Spring 2020
Similar Medication Names	Ancef, Ansaid, meloxicam oral
Clinical Use Evaluation	
Common Adverse Effects	≥ 2%: constipation, increased GGT, and anemia
Severe Adverse Effects	Hepatotoxicity, hemorrhage, severe skin reactions
Severe Drug-Drug Interactions	Drugs that interfere with hemostasis; ACE inhibitors, ARBs, or beta-blockers; diuretics
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	CBC and chemistry periodically if patient is receiving long-term NSAID therapy; IV meloxicam is not indicated for long-term use.
Used in Pediatric Areas	Safety and efficacy have not been established.
Renal or Hepatic Dosing	IV meloxicam has not been studied in hepatic impairment; monitor for adverse events in patients with severe hepatic impairment. IV meloxicam is not recommended in patients with moderate to severe renal impairment; it is contraindicated in patients with renal insufficiency who are at risk for renal failure due to volume depletion.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	<p>Contraindications: hypersensitivity; history of allergic-type reactions to aspirin or other NSAIDs; use in the setting of coronary artery bypass graft surgery; and moderate to severe renal insufficiency patients who are at risk for renal failure due to volume depletion.</p> <p>Warnings: class NSAID warnings including cardiovascular risk, gastrointestinal risk, hepatotoxicity, hypertension, heart failure and edema, renal toxicity and hyperkalemia; anaphylactic reactions; exacerbation of asthma related to aspirin sensitivity; serious skin reactions; premature closure of fetal ductus arteriosus; hematologic toxicity; and masking of inflammation and fever.</p> <p>Patient must be well hydrated prior to administration to reduce the risk of renal toxicity.</p> <p>In suspected or known poor CYP2C9 metabolizers consider dose reduction and monitor for adverse effects.</p>
Special administration technique or considerations	Administer by IV bolus injection over 15 seconds. Median time to meaningful pain relief is 2 to 3 hours, therefore a non-NSAID with a rapid onset of action may be needed in some patients.
Prepared by	Terri Levien
Source	Anjeso (meloxicam) [prescribing information]. Malvern, PA: Baudax Bio, Inc.; February 2020.

Bempedoic Acid / Nexletol / Esperion Therapeutics	
Generic Name / Brand Name / Company	Bempedoic Acid / Nexletol / Esperion Therapeutics
Date of approval	2/21/20
Drug Class (Mechanism of Action if novel agent)	Adenosine triphosphate-citrate lyase (ACL) inhibitor
Indication	Adjunct therapy to diet and maximally tolerated statin therapy for treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Tablets: 180 mg
Common Dose/sig	180 mg orally once daily
DEA Schedule	None
Date of market availability	3/30/20
Similar Medication Names	Nexium
Clinical Use Evaluation	
Common Adverse Effects	≥ 2%: Upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes.
Severe Adverse Effects	Tendon rupture, gout, benign prostatic hyperplasia, and atrial fibrillation.
Severe Drug-Drug Interactions	Avoid concomitant use with simvastatin doses greater than 20 mg or pravastatin doses greater than 40 mg.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Uric acid levels, serum lipids
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustment needed for mild to moderate renal impairment. Drug was not studied in end stage renal disease. No dosage adjustment needed for mild to moderate hepatic impairment (Child-Pugh A or B). Drug was not studied in severe hepatic disease.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: -Hyperuricemia: Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia and initiate treatment with urate lowering therapy as appropriate. -Tendon rupture: Tendon rupture has occurred. Discontinue at the first sign of tendon rupture. Avoid in patients who have a history of tendon disorders/tendon rupture.
Special administration technique or considerations	Can be taken with or without food.
Prepared by	
Source	<i>Nexletol</i> (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; February 2020.

Eptinezumab-jjmr / Vyepti / Lundbeck Seattle BioPharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Eptinezumab-jjmr / Vyepti / Lundbeck Seattle BioPharmaceuticals, Inc.
Date of approval	2/21/20
Drug Class (Mechanism of Action if novel agent)	CGRP antagonist; binds CGRP ligand preventing activity at receptor
Indication	Prevention of migraine in adults
Comparative agent – Therapeutic interchange?	Erenumab, fremanezumab, galcanezumab
Dosage forms/strengths	Injection: 100 mg/mL in single-dose vial
Common Dose/sig	100 mg as IV infusion every 3 months; some patients may benefit from 300 mg dosage.
DEA Schedule	None
Date of market availability	April 2020
Similar Medication Names	Eptifibatide, Vyzulta
Clinical Use Evaluation	
Common Adverse Effects	≥2%: nasopharyngitis, hypersensitivity
Severe Adverse Effects	Angioedema
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy have not been established.
Renal or Hepatic Dosing	No dosage adjustments are required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: hypersensitivity Warnings: hypersensitivity, including angioedema, urticaria, facial flushing and rash have occurred.
Special administration technique or considerations	Requires dilution in 100 mL 0.9% Sodium Chloride Injection, USP, and administration through an infusion set with 0.2 micron or 0.22 micron in-line or add-on sterile filter. Infuse over 30 minutes.
Prepared by	Terri Levien
Source	Vyepti (eptinezumab-jjmr) [prescribing information]. Lundbeck Seattle BioPharmaceuticals, Inc.; February 2020.

Amisulpride / Barhemsys / Acacia Pharma LTD	
Generic Name / Brand Name / Company	Amisulpride / Barhemsys / Acacia Pharma LTD
Date of approval	2/26/20
Drug Class (Mechanism of Action if novel agent)	Antiemetic; selective dopamine-2 and dopamine-3 antagonist
Indication	Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class. Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.
Comparative agent – Therapeutic interchange?	Alternative antiemetics; none are selective dopamine antagonists
Dosage forms/strengths	Injection: 5 mg/2 ml (2.5 mg/ml) single-dose vial
Common Dose/sig	Prevention of PONV: 5 mg single IV injection infused over 1 to 2 minutes at induction of anesthesia. Treatment of PONV: 10 mg single IV injection infused over 1 to 2 minutes in the event of nausea and/or vomiting after a surgical procedure.
DEA Schedule	None
Date of market availability	Second half of 2020
Similar Medication Names	None identified
Clinical Use Evaluation	
Common Adverse Effects	≥ 2% in prevention of PONV: Increased blood prolactin concentrations, chills, hypokalemia, procedural hypotension, and abdominal distension. ≥ 2% in treatment of PONV: Infusion site pain.
Severe Adverse Effects	Post-market reporting included: agranulocytosis, increased hepatic enzymes, torsades de pointes, and seizure.
Severe Drug-Drug Interactions	Dopamine agonists: avoid levodopa. Drugs prolonging the QT interval.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Renal: No dose adjustment is necessary in mild to moderate renal impairment. Avoid in patients with severe renal impairment (eGFR<30 mL/min/1.73 m ²).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with known hypersensitivity to amisulpride. Warnings: -Causes dose and concentration dependent QT interval prolongation. Avoid in patients with congenital long QT syndrome and in patients taking droperidol. Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders; electrolyte abnormalities; congestive heart failure; and in patients with other medical conditions known to prolong the QT interval.
Special administration technique or considerations	Sensitive to photodegradation; administer within 12 hours of removal of the vial from the protective carton. Dilution not required. Infuse over 1 to 2 minutes. May flush intravenous line with Water for Injection, 5% Dextrose Injection, or 0.9% Sodium Chloride Injection before or after administration.
Prepared by	Tracie Comer
Source	Barhemsys (amisulpride) [prescribing information]. Indianapolis, IN: Acacia Pharma Inc.; February 2020.

Rimegepant / Nurtec ODT / Biohaven Pharmaceuticals	
Generic Name / Brand Name / Company	Rimegepant / Nurtec ODT / Biohaven Pharmaceuticals
Date of approval	2/27/20
Drug Class (Mechanism of Action if novel agent)	CGRP antagonist
Indication	Acute treatment of migraine with or without aura in adults.
Comparative agent – Therapeutic interchange?	Ubrogepant
Dosage forms/strengths	Orally disintegrating tablet: 75 mg
Common Dose/sig	One 75 mg orally disintegrating tablet taken orally. Maximum dose in a 24-hour period is 75 mg.
DEA Schedule	None
Date of market availability	Early March 2020
Similar Medication Names	Nortrel, rimantadine, ubrogepant
Clinical Use Evaluation	
Common Adverse Effects	≥1%: nausea
Severe Adverse Effects	Severe rash
Severe Drug-Drug Interactions	<ul style="list-style-type: none"> - Avoid concomitant administration with strong inhibitors of CYP3A4; Avoid another dose of rimegepant within 48 hours when it is concomitantly administered with moderate inhibitors of CYP3A4 - Avoid concomitant administration with strong or moderate inducers of CYP3A - Avoid concomitant administration with inhibitors of P-gp or BCRP
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and effectiveness in pediatric patients have not been established.
Renal or Hepatic Dosing	<ul style="list-style-type: none"> - No dosage adjustment is required in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment. Plasma concentrations of rimegepant were significantly higher in subjects with severe (Child-Pugh C) hepatic impairment. Avoid use in patients with severe hepatic impairment - No dosage adjustment is required in patients with mild, moderate, or severe renal impairment. Rimegepant has not been studied in patients with end-stage renal disease and in patients on dialysis. Avoid use in patients with end-stage renal disease (CLcr < 15 mL/min)
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	<p>Contraindication: hypersensitivity</p> <p>Warnings: hypersensitivity reactions, including delayed reactions, have occurred</p>
Special administration technique or considerations	As soon as the blister is opened, remove the ODT and place on the tongue; alternatively, the ODT may be placed under the tongue. The safety of treating more than 15 migraines per 30-day period has not been studied.
Prepared by	Jesse Tegtmeyer
Source	Nurtec ODT (rimegepant) [prescribing information]. New Haven, CT: Biohaven Pharmaceuticals, Inc.; February 2020.